PCT/JP2003/013937

Translation

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference IS-08PCT	**FOR FURTHER ACTION**	See Form PCT/IPEA/416
International application No. PCT/JP2003/013937	International filing date (*day/month/year*) 30 October 2003 (30.10.2003)	Priority date (*day/month/year*) 30 October 2002 (30.10.2002)
International Patent Classification (IPC) or national classification and IPC G01N 33/50, 33/15, 33/566, A61K67/027, 31/44, 45/00, 38/17, 48/00, A61P 29/00, 37/02, 37/06, C07K 16/18, C12N 15/00		
Applicant ISHIHARA SANGYO KAISHA, LTD.		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 7 sheets, including this cover sheet.

3. This report is also accompanied by ANNEXES, comprising:

   a. ☐ *(sent to the applicant and to the International Bureau)* a total of _____ sheets, as follows:

      ☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).

      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.

   b. ☒ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) FD 1 , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

- ☒ Box No. I Basis of the report
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

Date of submission of the demand 12 March 2004 (12.03.2004)	Date of completion of this report 01 July 2004 (01.07.2004)
Name and mailing address of the IPEA/JP Facsimile No.	Authorized officer Telephone No.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International Application No.
PCT/JP2003/013937

Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This report is based on translations from the original language into the following language _____, which is language of a translation furnished for the purpose of:

☐ international search (under Rules 12.3 and 23.1(b))

☐ publication of the international application (under Rule 12.4)

☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

☒ The international application as originally filed/furnished

☐ the description:

pages _____, as originally filed/furnished

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____

☐ the claims:

pages _____, as originally filed/furnished

pages* _____, as amended (together with any statement) under Article 19

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____

☐ the drawings:

pages _____, as originally filed/furnished

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____

☒ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____

☐ the claims, Nos. _____

☐ the drawings, sheets/figs _____

☐ the sequence listing *(specify)*: _____

☐ any table(s) related to sequence listing *(specify)*: _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

☐ the description, pages _____

☐ the claims, Nos. _____

☐ the drawings, sheets/figs _____

☐ the sequence listing *(specify)*: _____

☐ any table(s) related to sequence listing *(specify)*: _____

* *If item 4 applies, some or all of those sheets may be marked "superseded."*

INTERNATIONAL PRELIM[redacted]Y REPORT ON PATENTABILITY

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Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application.

☒ claims Nos. 13-17, 21-24, (part of) 28-31

because:

☐ the said international application, or the said claims Nos. _____ relate to the following subject matter which does not require an international preliminary examination *(specify)*:

☒ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. 13-17, 21-24, (part of) 28-31 are so unclear that no meaningful opinion could be formed *(specify)*:

(See attached sheet)

☐ the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. 13-17, 21-24, (part of) 28-31 .

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form
- ☐ has not been furnished
- ☐ does not comply with the standard

the computer readable form
- ☐ has not been furnished
- ☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ see Supplemental Box for further details.

INTERNATIONAL PRELIMIN[redacted] REPORT ON PATENTABILITY

International [redacted]plication No.
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Box No. IV Lack of unity of invention

1. ☐ In response to the invitation to restrict or pay additional fees the applicant has:

   ☐ restricted the claims.

   ☐ paid additional fees.

   ☐ paid additional fees under protest.

   ☐ neither restricted nor paid additional fees.

2. ☒ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is

   ☐ complied with.

   ☒ not complied with for the following reasons:

The inventions of claims 1-12 concern a screening method that focuses on the mutual interaction of human Rap1 and human p30 (RAPL).

The inventions of claims 18-20 are inventions that concern monoclonal antibodies that bind to human p30 (RAPL).

The inventions of claims 25-27 concern a transgenic animal in which the expression of mouse RAPL is regulated.

The invention of claim 32 is a compound (a substance that inhibits the binding of human Rap1 and human p30 (RAPL).

These groups of inventions are not found to have no common special technical feature, and therefore do not satisfy the requirement for unity of invention.

4. Consequently, this report has been established in respect of the following parts of the international application:

   ☒ all parts.

   ☐ the parts relating to claims Nos. _____.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International Application No.
PCT/JP03/13937

Box No. V **Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims	1-12, 18-20, 25-27	YES
	Claims	28-32	NO
Inventive step (IS)	Claims	1-12	YES
	Claims	18-20, 25-32	NO
Industrial applicability (IA)	Claims	1-12, 18-20, 25-32	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

Document 1: JP 2002-530077 A (Incyte Pharmaceuticals, Inc.) September 17, 2002, SEQ ID NO: 8, SEQ ID NO: 16, Par. Nos. 0074 to 0076

Document 2: JP 6-135934 A (ISHIHARA SANGYO KAISHA, LTD.) May 17, 1994, Par. No. 0115

Document 3: WO 98/37887 A1 (ISHIHARA SANGYO KAISHA, LTD.) September 3, 1998, Claims

Document 4: EP 465913 A2 (ISHIHARA SANGYO KAISHA, LTD.) January 15, 1992, page 51, lines 24 to 39

Document 5: WO 01/056570 A1 (ISHIHARA SANGYO KAISHA, LTD.) August 9, 2001, page 8, line 5 from the bottom to line 2 from the bottom

Document 6: WO 01/056568 A1 (ISHIHARA SANGYO KAISHA, LTD.) August 9, 2001, page 10, line 3 from the bottom to page 11, line 6

Claims 1-12

None of the documents cited in the international search report describes or suggests focusing on the interaction between a polypeptide such as that of SEQ ID NO: 2 with a polypeptide such as that of SEQ ID NO: 4, and screening for agonists or antagonists of that interaction.

Therefore, the inventions of claims 1-12 are novel and involve an inventive step.

(Continued on the attached sheet)

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Supplemental Box Relating to Sequence Listing

Continuation of Box No. 1, item 2:

1. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this report was established on the basis that of:

   a. type of material

   ☒ a sequence listing

   ☐ table(s) related to the sequence listing

   b. format of material

   ☐ in written format

   ☒ in computer readable form

   c. time of filing/furnishing

   ☐ contained in the international application as filed

   ☒ filed together with the international application in computer readable form

   ☐ furnished subsequently to this Authority for the purpose of search and/or examination

   ☐ received by this Authority as an amendment* on _____

2. ☒ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

3. Additional comments:

** If item 4 in Box No. I applies, the listing and /or table(s) related thereto, which form part of the basis of the report, may be marked "superseded".*

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.
Continuation of Box III, V:

(attached sheet)

<Box III>

The inventions of claims 13-17 concern substances obtained as a result of performing a screening method, but the description of specifically what kind of substances are obtained when the screening method is performed is unclear, and the inventions are not disclosed to the extent that a significant search is possible.

The inventions of claims 21-24 concern polypeptides that function intracellularly as a dominance suppression type for a specific polypeptide, but the description of what kind of substance functions as a dominance suppression type for a specific polypeptide is unclear, and the inventions are not disclosed to the extent that a significant search is possible.

The inventions of claims 28-31 concern compounds that inhibit the binding of Rap1 and p30 (RAPL), but the description of the invention is unclear because of multiple selective branches, and it is also unclear whether this binding inhibition effect is present in all these compounds. Therefore, parts of these inventions are not disclosed to the extent that a significant search is possible.

<Box V>

Claims 18-20

Document 1 cited in the international search report states that polypeptides such as the one identified by SEQ ID NO: 4 are associated with disease. In this context, because it is obvious to persons skilled in the art from the molecular weight that the polypeptide has antigenicity, it is easy for persons skilled in the art to prepare a monoclonal antibody to the polypeptide use it for diagnostic purposes.

As a result, the inventions of claims 18-20 lack an inventive step.

Claims 25-27

Document 1 cited in the international search report describes polypeptides such as the one identified by SEQ ID NO: 10. Moreover, in general, a transgenic mouse is often prepared by manipulating the expression of a target polypeptide. Therefore, it is easy for persons skilled in the art to prepare a transgenic mouse in which the expression of this polypeptide is regulated.

As a result, the inventions of claims 25-27 lack an inventive step.

Claims 28-32

Documents 2-6 cited in the international search report describe compounds such as those in the inventions of claims 28-32. The inventions of claims 28-32 are inventions concerning compounds themselves. The compounds themselves are identical to those described in documents 2-6 regardless of whether the fact that they have a specific binding inhibition function was previously known or not.

As a result, the inventions of claims 28-32 lack an inventive step.

(End)